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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,137	11/25/2003	Charles D. Claude	50623.339	9454

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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,137	Applicant(s) CLAUDE ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 15-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4-26-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response and election of Group IV, claims 11 – 14 with traverse, is acknowledged. Claims 1 – 30 are pending in this action.

Election/Restrictions

Applicant's election with traverse of Group IV in the reply filed on 2/26/2007 is acknowledged. The traversal is on the ground(s) that all of the claims are related to the polymer of claim 1 and can be examined together. This is not found persuasive. The response is not well understood, since claim 1 is drawn to a polymer composition, and not to a polymer. Irrespective of this, the argument does not address the merits of the restriction requirement, that is, the statements in the office action mailed 2/1/2007 that the various Groups are separate or distinct. Since no specific error in the restriction requirement was pointed out, the argument cannot be persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Pursuant to the election, claims 1 – 10 and 15 – 30 are **withdrawn** from consideration as being drawn to non-elected inventions. Claims 11 – 14 are considered on the merits below.

With regard to the election of species, a search of the elected invention found that the elected species of the elected invention is free of the art. As such, the search was expanded to include the generic species of polysulfones.

Claim Objections

Claims 11 – 14 are objected to for directly or ultimately depending on withdrawn claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recites "sirolimus derivative". However, it is not clear what compounds are "derivatives" of sirolimus, as claimed. Accordingly, the artisan would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 – 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,013,099 to Dinh et al.

Dinh teaches a stent comprising a cylindrical body, a coating layer of a non-fibrin polymer with fibrin incorporated therein and a therapeutic salt disposed in the film (claim 6). The porous polymer layer is a polysulfone in one embodiment (claim 8), and the therapeutic salt is, in one embodiment, heparin (claim 11). Heparin and fibrin are both drugs and are believed to be elastomeric polymers. The stent is a drug eluting stent, since it contains drugs (heparin) which are delivered from the stent (see abstract).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 – 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,013,099 to Dinh et al in view of EP 0 897 595 (the '595 reference or '595), of record.

The teachings of Dinh are discussed above.

What is lacking is an explicit teaching of an elastomer.

The '595 reference suggests the use of elastomers in polymer coatings for stents (claim 5). Note that the artisan would recognize that all of the polymers of this claim are elastomers, although this is not explicitly stated.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to include elastomers in the stent coating of Dinh. The motivation comes from '595, who suggests this use for elastomers. Since this is a suggestion from the art, the artisan would enjoy a reasonable expectation of success.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,013,099 to Dinh et al in view of US 6,258,121 to Yang et al.

The teachings of Dinh are discussed above.

What is lacking is a teaching of the drugs of instant claim.

Yang teaches that the drug Taxol (paclitaxel) is recognized to be useful when incorporated in polymer coatings of stents (abstract).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use paclitaxel in the stent of Dinh. The motivation comes from Yang, who teaches the art-recognized suitability of paclitaxel for this purpose. Because such suitability is recognized in the art, the artisan would enjoy a reasonable expectation of success.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,013,099 to Dinh et al in view of EP 0 897 595 and in further view of US 6,258,121 to Yang et al.

The teachings of Dinh and '595 are discussed above.

What is lacking is a teaching of the drugs of instant claim.

Yang teaches that the drug Taxol (paclitaxel) is recognized to be useful when incorporated in polymer coatings of stents (abstract).

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It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use paclitaxel in the stent of Dinh. The motivation comes from Yang, who teaches the art-recognized suitability of paclitaxel for this purpose. Because such suitability is recognized in the art, the artisan would enjoy a reasonable expectation of success.

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
Art Unit 1615


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